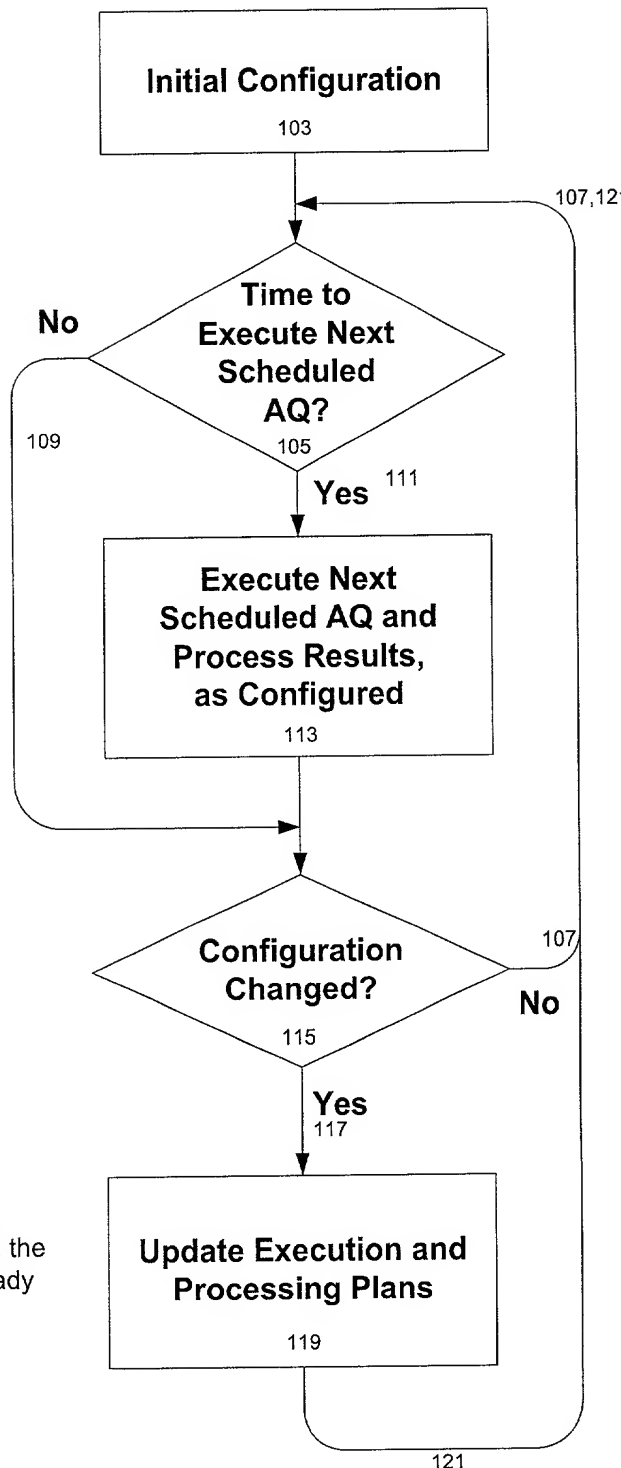


103: The **Initial Configuration** is used to define the execution and processing plans, including the following:

- **Query (search / trigger criteria)**
- **Admin Scope**
- **Admin Schedule**
- **Admin Activity**
- **Admin Query**

105: In this step the next scheduled **Admin Query**, is executed, querying the database, searching for records meeting the given **Admin Query** conditions, and processing all PRs in the **Result Set**.

119: Upon detection of changes in the execution and, or the processing plans, the system adopts the new plans and is ready to continue with the next cycle



105: In this step the next Admin Query, if any, is executed, querying the database, searching for records meeting the given **Admin Query** conditions.

115: A periodical check for whether the current execution plan and process plan have changed, e.g.,

- Removal of exiting **AQs**.
- Changes in Admin Schedule.
- Changes in Admin Scope (adding or removing Projects, i.e., work areas).
- New Admin Activities.
- New Notification Rules.

FIG. 1

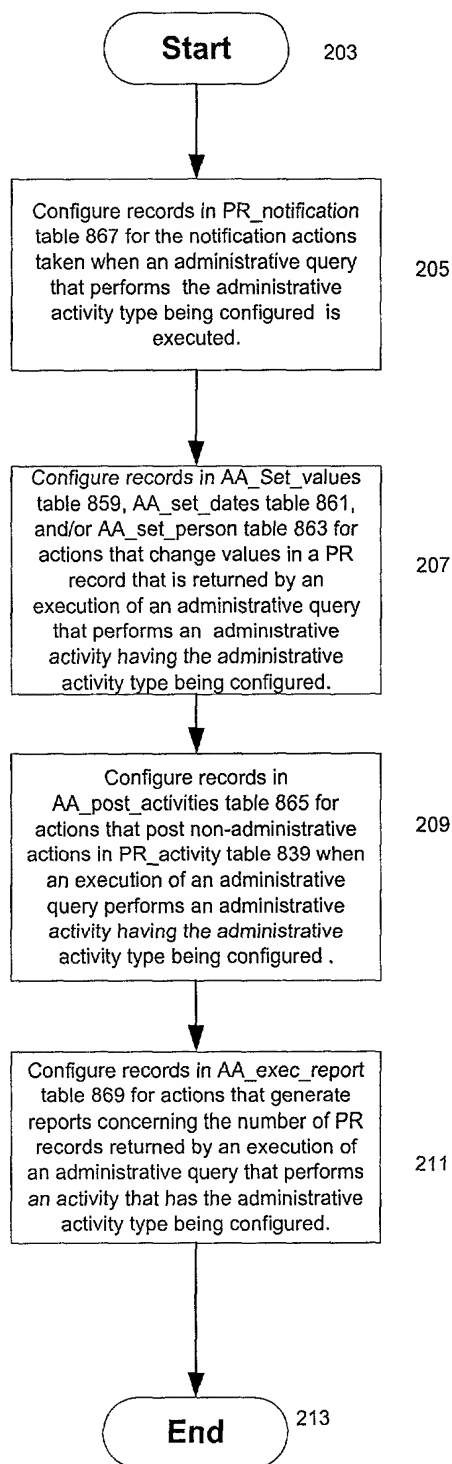


FIG. 2

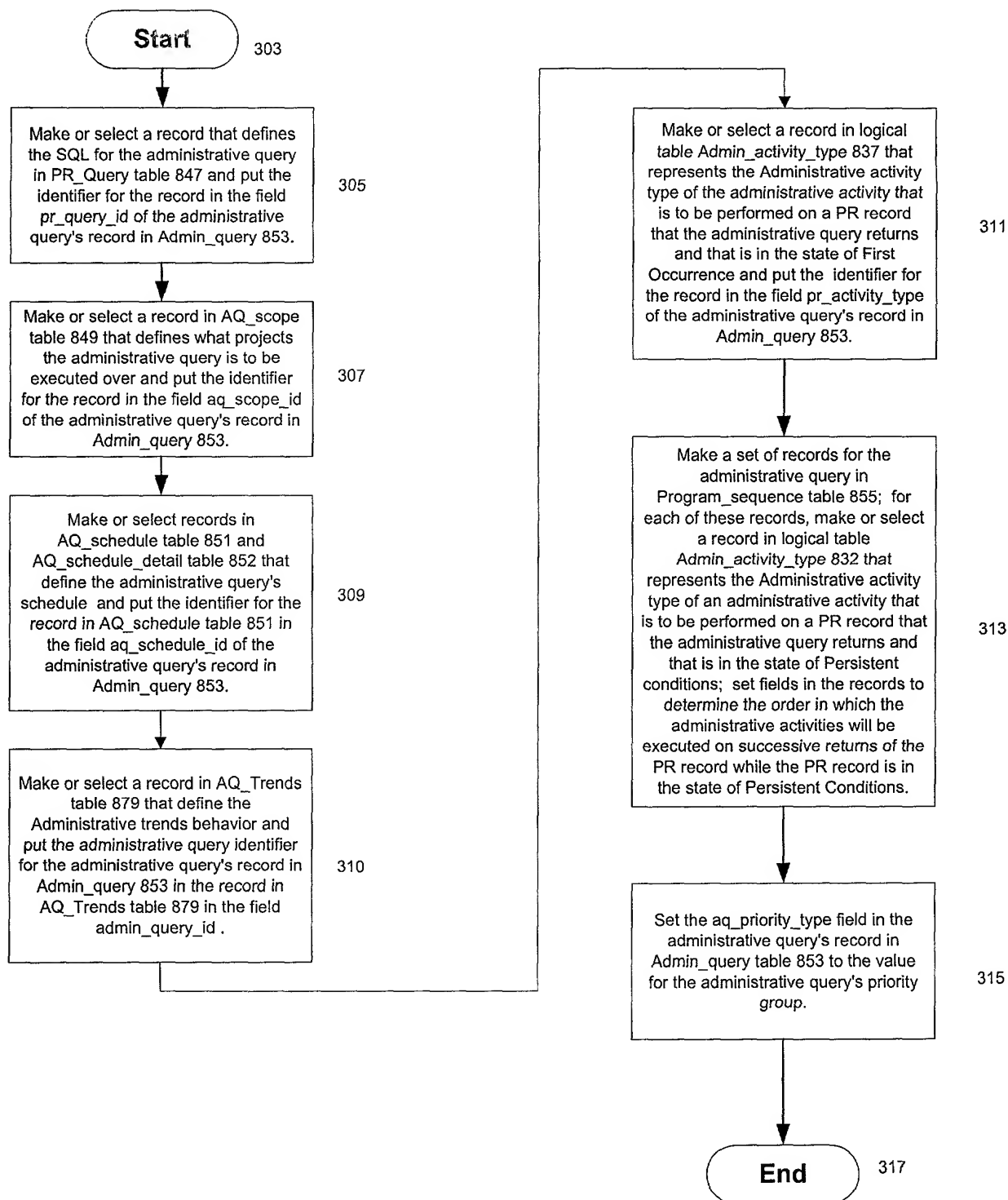
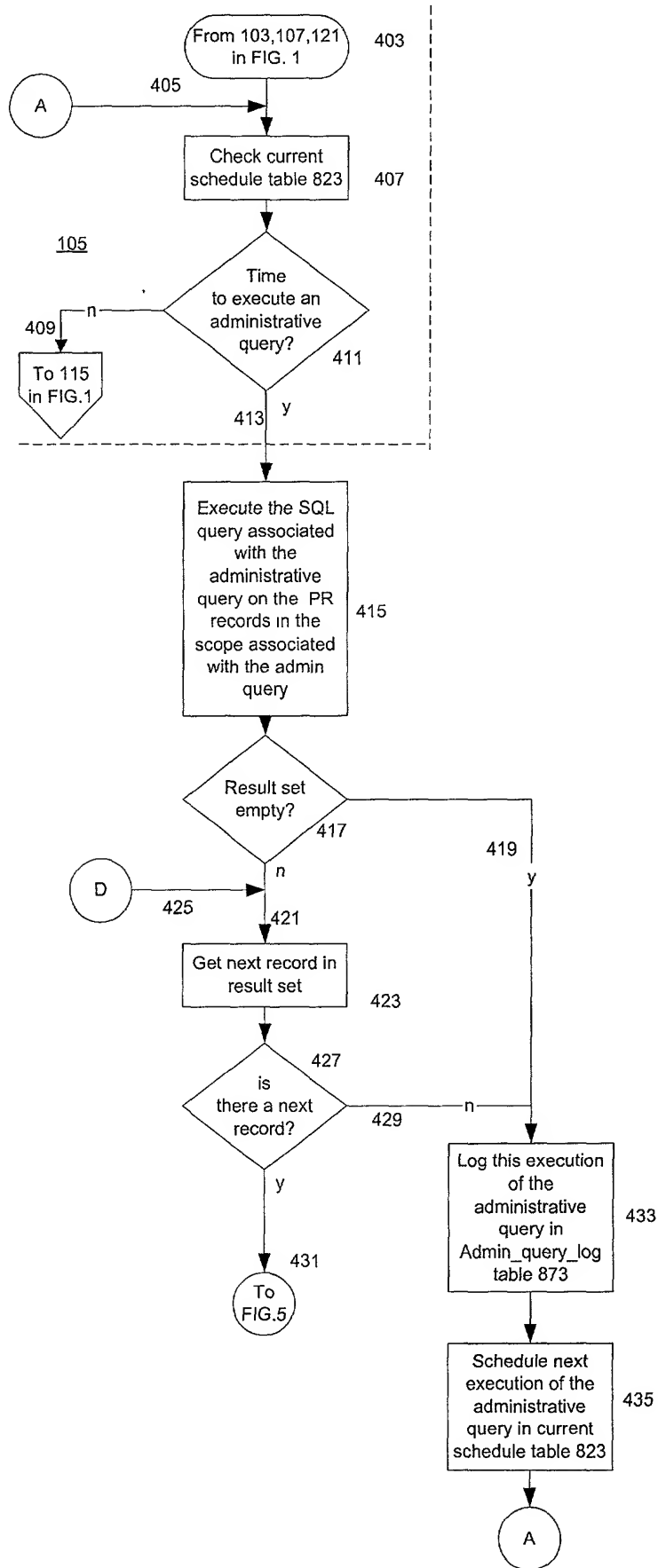
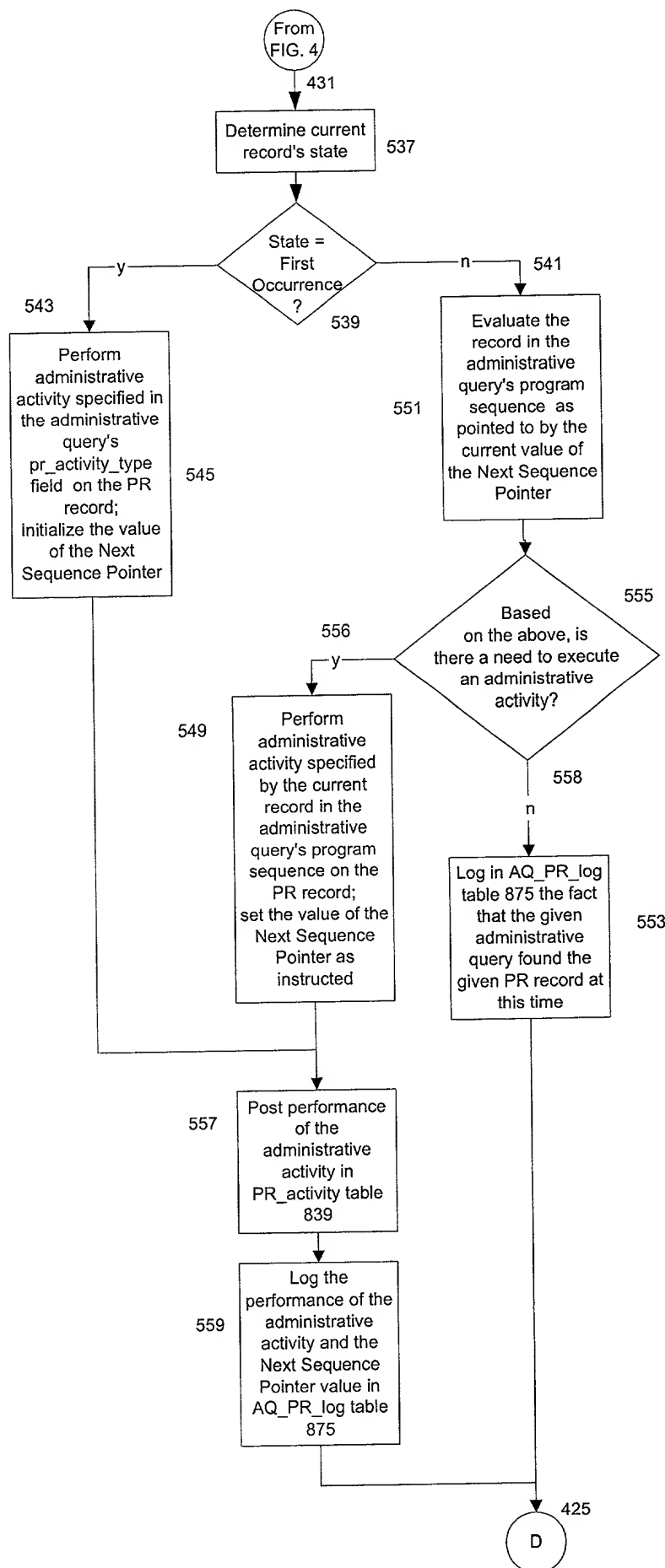


FIG. 3





501

FIG. 5

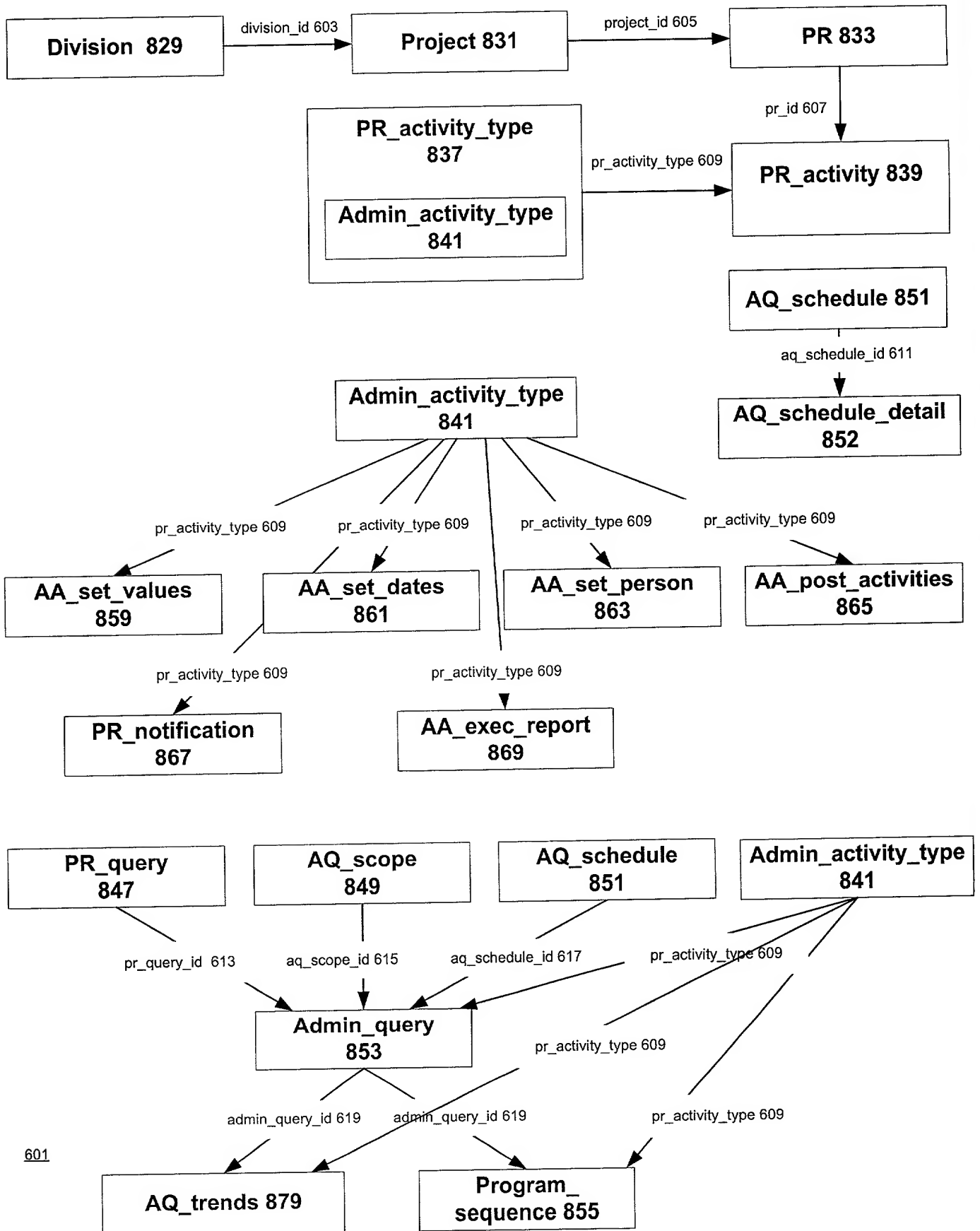


FIG. 6

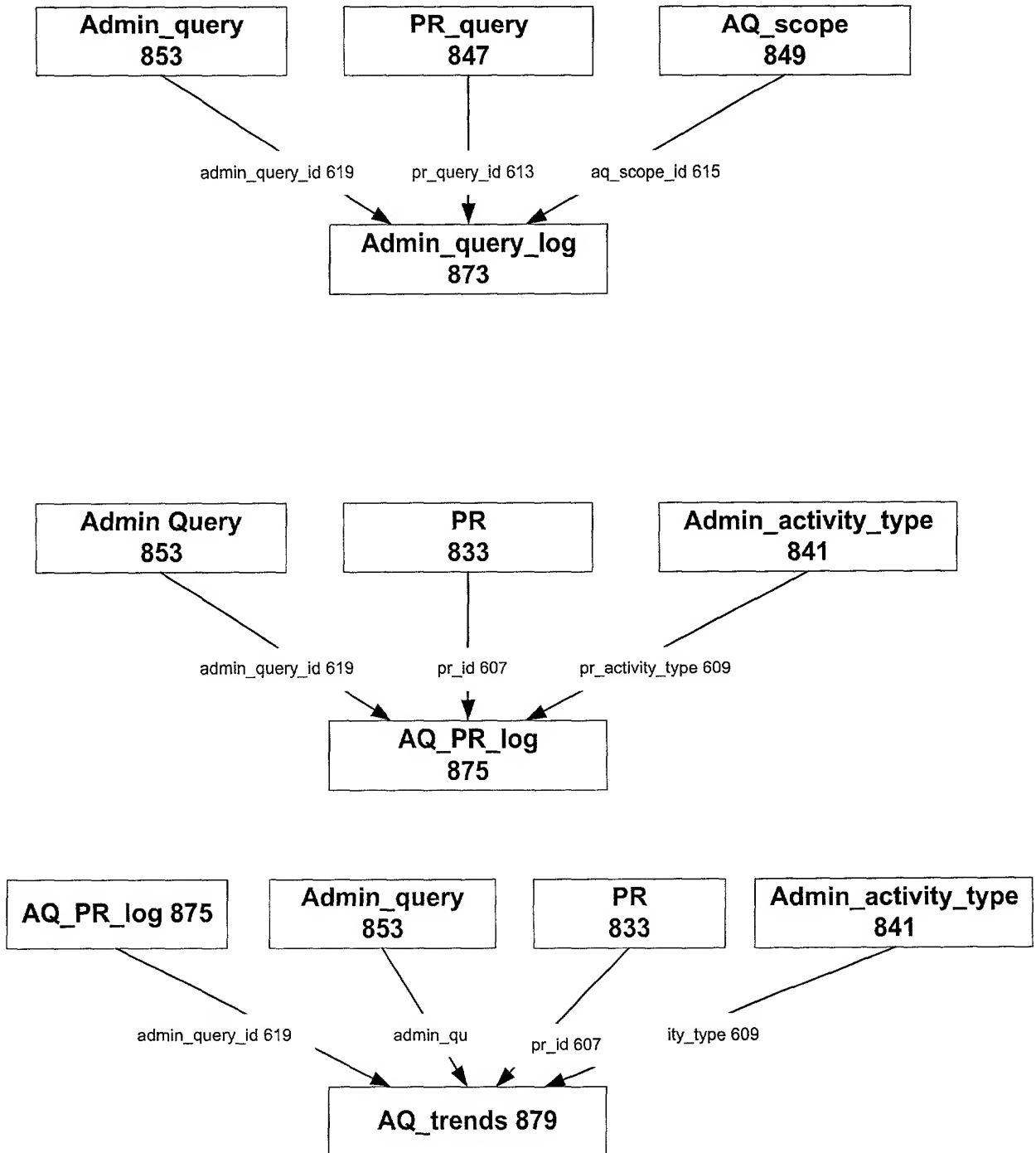


FIG. 7

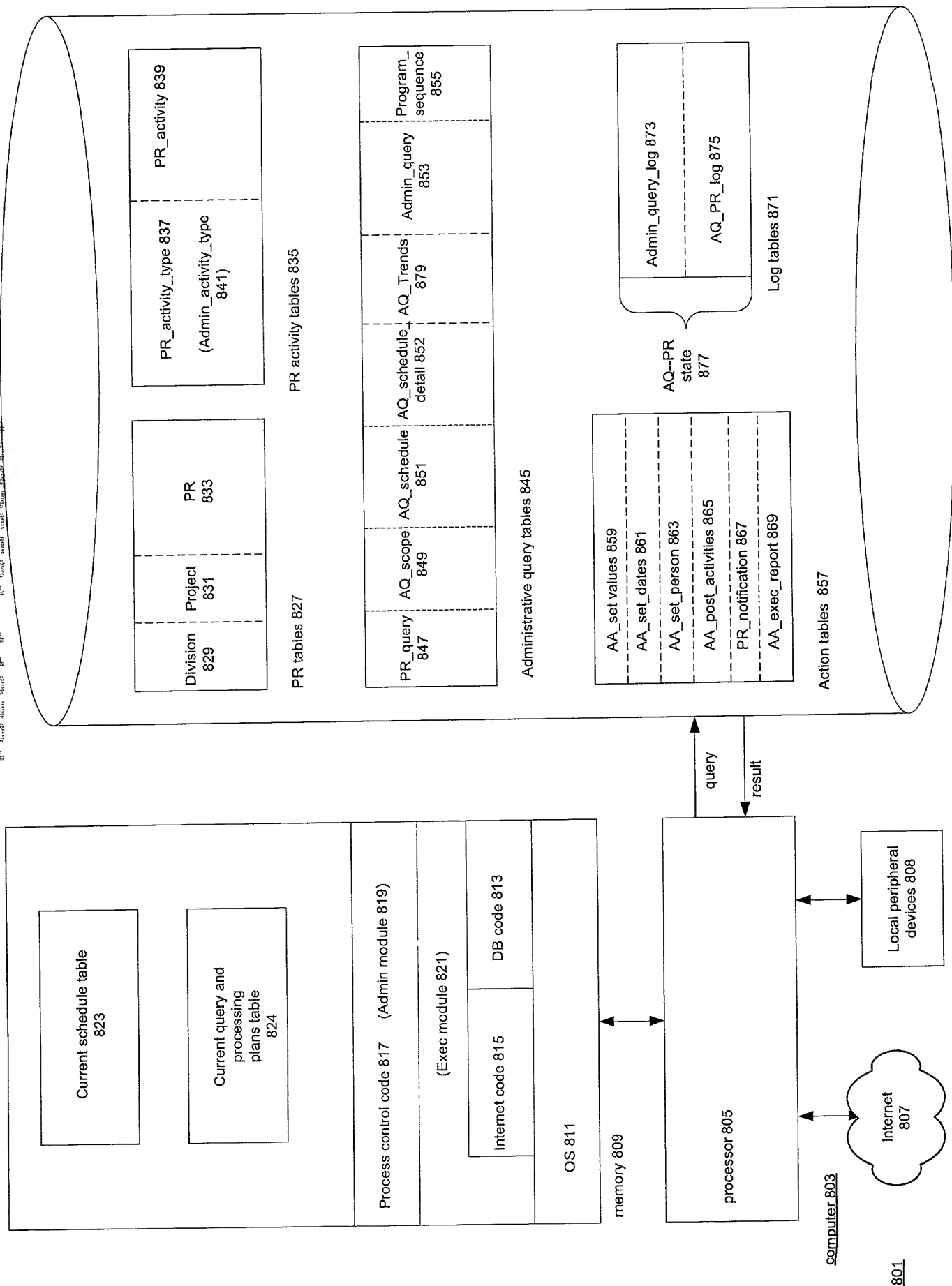


FIG. 8

DB system 825

10036591-110701

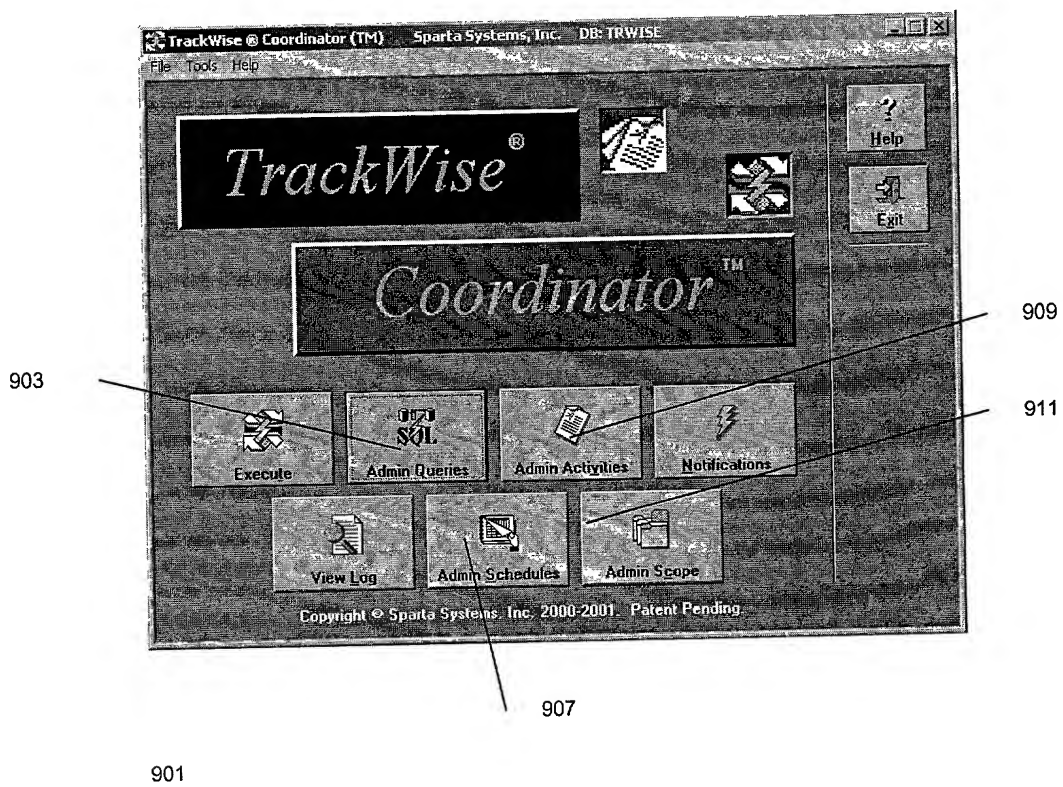
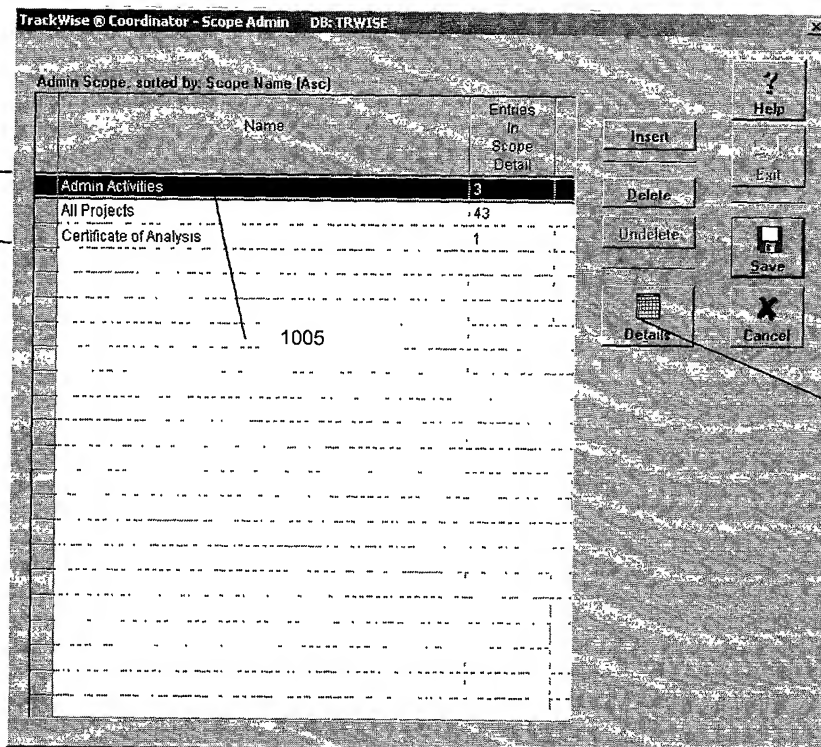


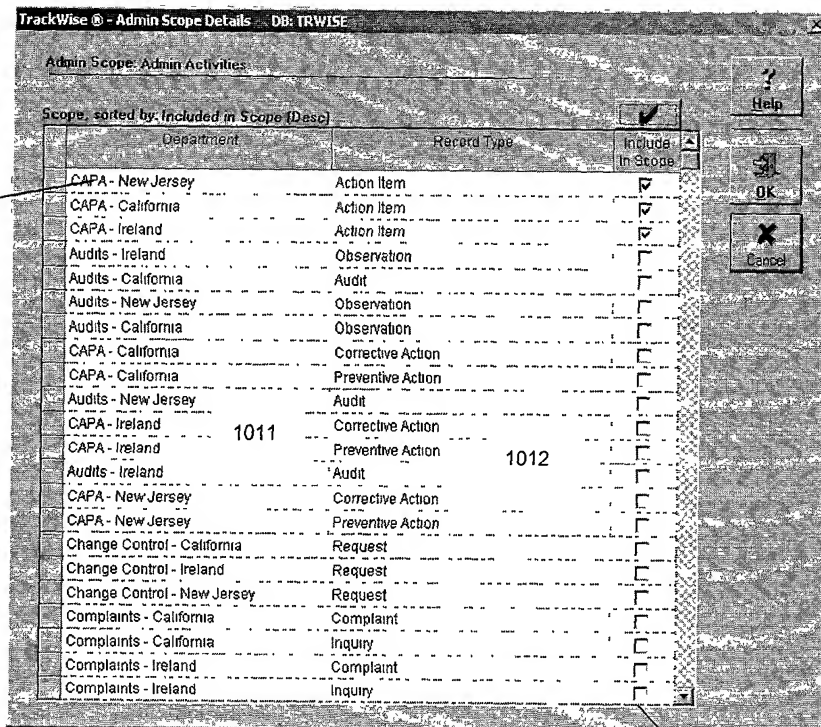
FIG. 9

1003



1001

1010



1009

1013

FIG. 10

[illegible]

Schedule Details - Monday Friday Every Two Hours DB: TRWISE

Admin Schedule: Monday Friday Every Two Hours

Schedule Details:

Day	Start Time	End Time	Time Interval
Sunday	8:00 AM	5:00 PM	120
Monday	8:00 AM	5:00 PM	120
Tuesday	8:00 AM	5:00 PM	120
Wednesday	8:00 AM	5:00 PM	120
Thursday	8:00 AM	5:00 PM	120
Friday	8:00 AM	5:00 PM	120
Saturday			

Buttons: Help, Exit, Clear, Copy to All, Edit

FIG. 11

1215
1217
1219
1221

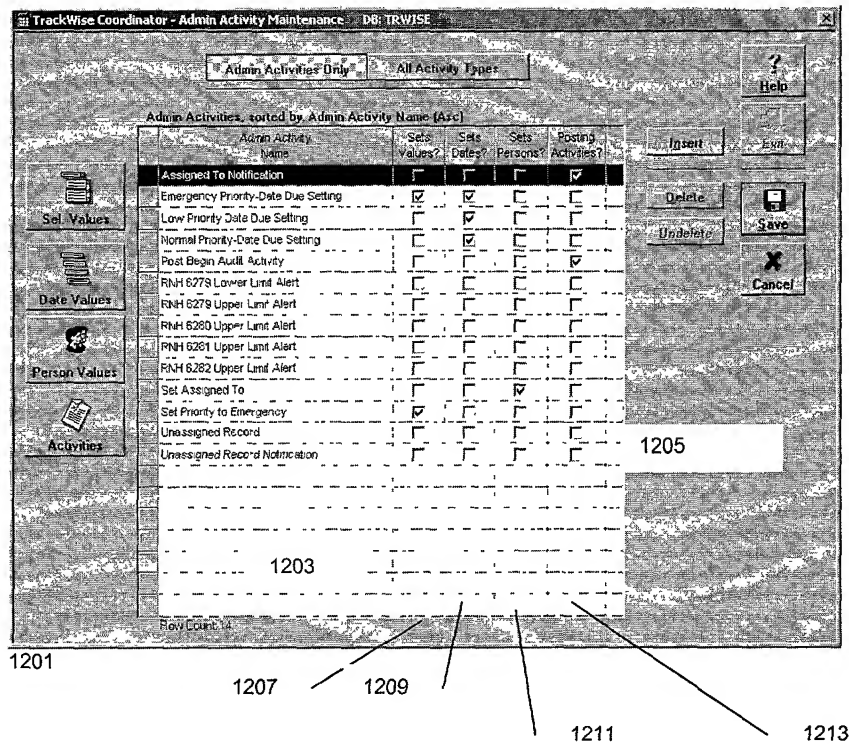


FIG. 12

FIG 13

1302

Administration of Setting Selection Values

Admin Activity: Set Priority to Emergency

Set values, sorted by Field Name (Asc)

Field Name to Set	Field Type	Operation	Set Values
Additional Samples Tested?	Selection		
Affected SOP	Selection		
Assessment Method	Selection		
Assignable Cause	Multi-Selection		
Condition	Selection		
Disposition of Samples	Selection		
Final Disposition	Selection		
Governing SOP	Selection		
Impact	Selection		
Location	Selection		
Mfg Stage	Selection		
Phase	Selection		
Priority	Selection	Set	Emergency
Product Family	Selection		
Product(s)	Multi-Selection		
Proposed Disposition	Selection		
Type	Selection		

1303 1305 1307 1309

1301

1306

Mfg Stage	Selection	
Phase	Selection	
Priority	Selection	Set Emergency
Product Family	Selection	Increment 1311
Product(s)	Multi-Selection	Set
Proposed Disposition	Selection	Clear
Type	Selection	

1310

Selection Values DB: TRWISF

Emergency
Low
Normal

1313

Help
OK
Cancel

FIG 13

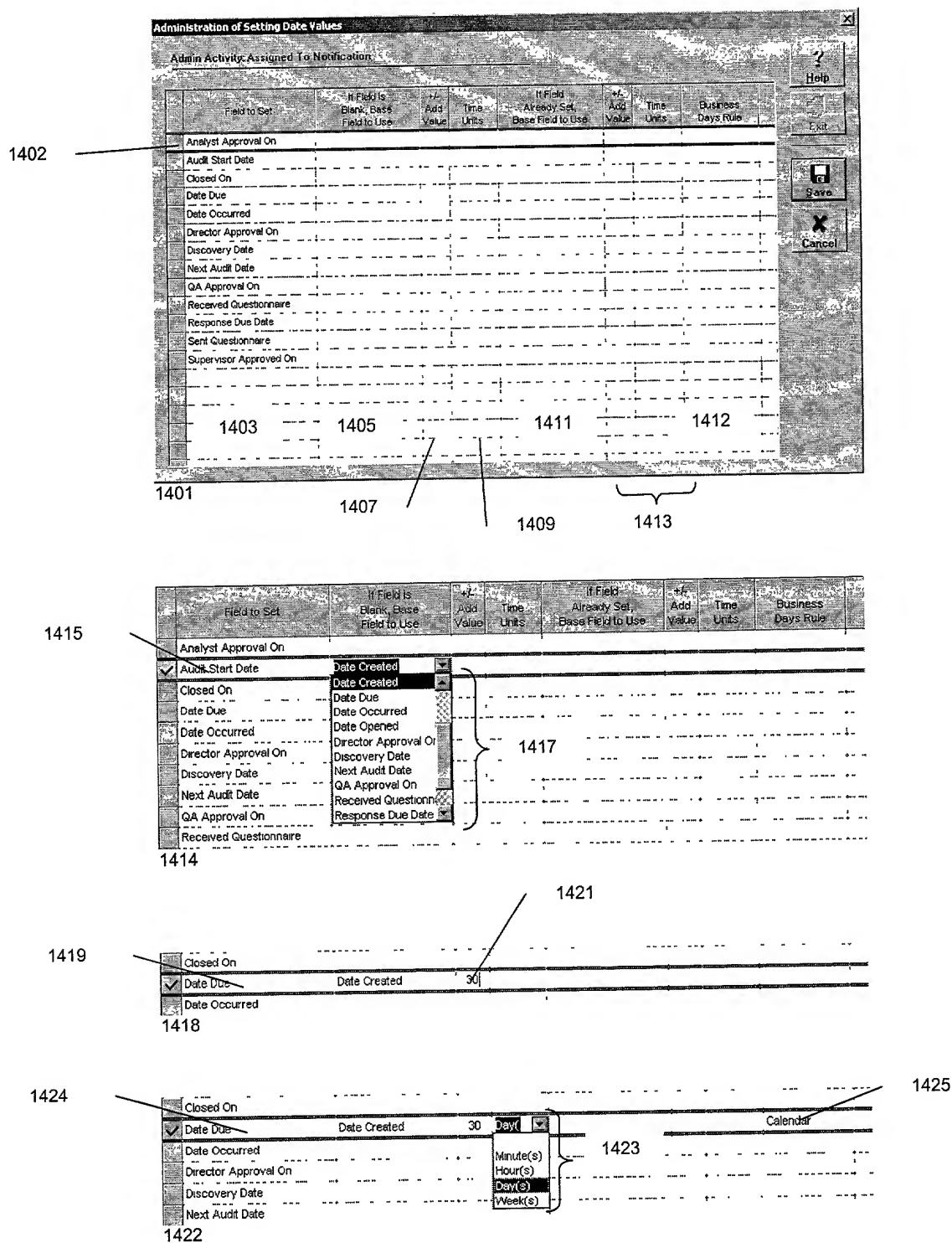


FIG. 14

1501

Administration of Setting Person Fields

Admin Activity: Set Assigned To

Field to Set	If Field Is Blank, Person to Set	If Field Is Blank, Person Role to Set	If Field Already Set, Person to Set	If Field Already Set, Person Role to Set
2nd Auditor				
Analyst Approval By				
Assigned To			Customer Support	
Closed By			Customer Support	
Contact			Developer	
Director Approval By			Project Leader	
Originator			Project Manager	
Person Notified				

1503 1505 1507 1509 1511

1513

1515

Help Exit Save Cancel

1517

Administration of Setting Person Fields

Admin Activity: Set Assigned To

Field to Set	If Field Is Blank, Person to Set	If Field Is Blank, Person Role to Set	If Field Already Set, Person to Set	If Field Already Set, Person Role to Set
2nd Auditor				
Analyst Approval By				
Assigned To			Benson, Harry	
Closed By				
Contact				

Help Exit Edit

FIG. 15

1602

Administration of Posting Activities

Admin Activity: Post Begin Audit Activity

Activity to Post	Posting Mode	Date Reference Field	% Value	Time Units	Business Days Rule	Responsible by Function	Responsible by Name
Action Item(s) Complete							
All Responses Received							
*Analyst Approval							
*Approve Corrective Action							
*Approve Preventative Action							
✓ Begin Audit	Perform						
Begin Change Control	Schedule						
Begin Investigation	Perform						
*Change Control Cancelled							
Change Request							
*Close							
*Close - Defer							
*Close - Reject							
Comments							
Commitment Initiated							
Complete							
Complete Commitment		1603				1609	1611
Complete Correspondence		1605					

Note: Color-coded Activity Types Require Electronic Signature and can therefore be posted as Scheduled only.

1601

1604

1607

1613

Administration of Posting Activities

Admin Activity: Post Begin Audit Activity

Activity to Post	Posting Mode	Date Reference Field	% Value	Time Units	Business Days Rule	Responsible by Function	Responsible by Name
Action Item(s) Complete							
All Responses Received							
*Analyst Approval							
*Approve Corrective Action							
*Approve Preventative Action							
✓ Begin Audit	Schedule	Current Date/Time	2	Day(s)	Calendar	Contract	
Begin Change Control							
Begin Investigation		1614				1615	
*Change Control Cancelled							
Change Request							
*Close							
*Close - Defer							
*Close - Reject							
Comments							
Commitment Initiated							
Complete							
Complete Commitment							
Complete Correspondence							

Note: Color-coded Activity Types Require Electronic Signature and can therefore be posted as Scheduled only.

FIG. 16

TrackWise ® - Admin Query Maintenance DB: TRWISE

Active Admin Queries Query Name (Asc)

Query Name	Triggered Activity	Admin Scope	Schedule	Priority Group	Program Entries
Emergency Priority	Emergency Priority-Data Due Setting	Admin Activities	Monday Friday Every Two Hours	2	1
Low Priority	Low Priority Date Due Setting	Admin Activities	Monday Friday Every Two Hours	2	1
Normal Priority	Normal Priority-Data Due Setting	Admin Activities	Monday Friday Every Two Hours	2	1
Over Due Records	Assigned To Notification	All Projects	Every Day, Every Minute	2	1
RNH 6279 <3.5	RNH 6279 Lower Limit Alert	Certificate of Analysis	Every Day, Once a Day	2	1
RNH 6279 >4.5	RNH 6279 Upper Limit Alert	Certificate of Analysis	Every Day, Once a Day	2	1
RNH 6380 > 8	RNH 6280 Upper Limit Alert	Certificate of Analysis	Every Day, Once a Day	2	1
RNH 6381 >5.5	RNH 6281 Upper Limit Alert	Certificate of Analysis	Every Day, Once a Day	2	1
RNH 6382 >1.6	RNH 6282 Upper Limit Alert	Certificate of Analysis	Every Day, Once a Day	2	1
Unassigned PRRs	Unassigned Record	Admin Activities	Monday Friday Every Two Hours	2	2

Row Count: 10

1702

1703

1705

1707

1709

1701

1711

1713

1712

1714

1717

1719

Program Sequence Details DB: TRWISE

Admin Query: Unassigned PRR

Program Sequence, sorted by Sequence Number (Asc) (no other sorting is available)

Seq No	Triggered Activity	Program Control: What to do after Executing the Current Sequence	Time Interval (in minutes)
1	Unassigned Record Notification Next - Advance to next sequence (wait given time interval)		120
2	Unassigned Record Notification Next - Advance to next sequence (wait given time interval)		60
3	Unassigned Record Notification Continue - Continue forever (wait given time interval)		30

1723

1727

1729

1731

1721

1725

FIG. 17